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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,753	07/13/2001	Robert T. Lyons	D-2973	3325

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EXAMINER
MAYES, LAURIE A

ART UNIT	PAPER NUMBER
1653	6

DATE MAILED: 07/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/904,753	LYONS, ROBERT T.	
	Examiner	Art Unit	
	Laurie Mayes	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *81-120* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *113-118* is/are allowed.

6)☒ Claim(s) *81-112,119 and 120* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Objections

Claims 87, 94, 100, 101, 119 and 120 are objected to as they contain sequences more than four amino acids in length and fail to recite "SEQ ID NO: ___". See 37 CFR 1.821-1.825. Also, some of the sequences in the body of the specification lack identifying SEQ ID NOS: (specification p. 5, line 8, for example).

Specification

The use of the trademarks TYLOXAPOL (p. 19, line13) and PLURONIC (p. 19, line 20) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claims 87, 94, 100, 101, 119 and 120 are objected to as they contain sequences more than four amino acids in length and fail to recite "SEQ ID NO: ___". See 37 CFR 1.821-1.825. Also, none of the sequences in the body of the specification is identified by a SEQ ID NO.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 82, 89, 96, 102, 108 and 114 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The language "less than about" is indefinite as it is

unclear which term controls the bounds of the claims. The term "about" means a range above and below a named limit while "less than" means below the named limit. Further, could the amount of the magainin component be less than 0%?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 81-86, 106 and 108-118 are rejected under 35 U.S.C. 102(b) as anticipated by Huth et al. (WO 96/25183; cited in IDS of paper # 4). Huth et al. teach an ophthalmic preservative solution (see claim 14 of Huth et al., last line) that could be used in a multidose format (p. 3, lines 10-15 and Ex. 3 of Huth et al.) comprising magainin antimicrobial peptides or a peptide mimetic of magainin (see claim 21 of Huth et al.) wherein said preparation is applied to the eye (see claim 12 or Huth et al.) and has a tonicity agent (p. 17, line 20 of Huth et al.) and buffers that act as pH adjustors (p. 17, line 21 of Huth et al.) and wherein the antimicrobial agent is present in a therapeutically effective amount of less than 10 mg per ml (p. 12, lines 25-29 also see the examples of Huth et al.).

Claims 81-83 and 88-93 are rejected under 35 U.S.C. 102(b) as being anticipated by Hunt (US 5,549,894). Hunt teaches an antimicrobial ophthalmic composition for contact lenses having a liquid phase (col. 6, lines 13-15) and comprising one active agent only (col. 9, lines 10-

11), for example, magainins, and a buffer to control the pH (col. 6, lines 25-26), wherein the active agent is present in an amount less than 10 milligrams per millimeter (col. 8, lines 32-35 and Example1; for example, .1 mg of active agent in 5-10 ml of liquid) and comprises water from an added saline solution (col. 8, lines 37-40). The antimicrobial activity prevents the growth of microbes and serves to preserve the ophthalmic solution.

Claims 81, 84-88, 91-94, 101, 104-106 and 110-112 are rejected under 35 U.S.C. 102(b) as being anticipated by Maloy (US 5,792,831). Maloy teaches an ophthalmic composition that is applied topically onto the eye (col. 29, lines 27-28 and col. 30, lines 53-55) (present claim 106) comprising a sole preservative (col. 28, lines 48-50 and Ex. 1), namely, therapeutically effective amount of a magainin antimicrobial peptide identical to SEQ ID NO: 4 (see copy of attached sequence alignment; SEQ ID NO: 2 and col. 31, line 56) in a distilled water solution which also may serve as a tonicity component (col. 32 line 14) (present claims 81, 84-88, 91-94, 101, 104, 105, 110-112). As Maloy teaches all of the elements of claims 81, 84-88, 91-94, 101, 104-106 and 110-112, these claims are anticipated under 35 U.S.C. 102(b).

Claims 95, 98 and 99 are rejected under 35 U.S.C. 102(e) as being anticipated by Deckers et al. (US 6,372,234). Deckers et al. teach an oil-in-water (col. 12, lines 41-43) antimicrobial ophthalmic composition, namely, liquid eye makeup remover (col. 24, lines 43-44) with a certain tonicity (present claim 98) wherein the composition comprises magainin (col. 22, lines 8-22) (present claim 99). Deckers et al. do not teach an ophthalmic preservative. The antimicrobial activity prevents the growth of microbes and serves to preserve the ophthalmic solution. As Deckers et al. teach all of the elements of claims 95, 98 and 99, these claims are anticipated under 35 U.S.C. 102(e).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 81, 84-88, 91-95, 98, 99, 101, 104-106 and 110-112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maloy in view of Stevenson et al. (Ophthalmology 2000 May; 107 (5):967-74; cited in IDS paper #4). Maloy teaches an ophthalmic composition that is applied topically onto the eye (col. 29, lines 27-28 and col. 30, lines 53-55) (present claim 106) comprising a sole preservative (col. 28, lines 48-50 and Ex. 1), namely, therapeutically effective amount of magainin antimicrobial peptide identical to SEQ ID NO: 4 (see copy of attached sequence alignment; SEQ ID NO: 2 and col. 31, line 56) in a distilled water solution which also may serve as a tonicity component (col. 32 line 14) (present claims 81, 84-88, 91-95, 101, 104, 105, 110-112). Maloy does not teach an oil-in-water emulsion.

Stevenson et al. teach an oil-in-water emulsion formulation to treat moderate-to-severe dry eye disease wherein the active agent cyclosporin in present in a therapeutically amount of a concentration of .05% (line 7), namely, liquid eye makeup remover (col. 24, lines 43-44) with a certain tonicity (present claim 98) wherein the composition comprises magainin (col. 22, lines 8-22) (present claim 99). Stevenson et al. do not teach a preparation containing a sole preservative or a peptide identical to SEQ ID NO: 4. Given the successful treatment of eye disease by using an oil-in-water emulsion comprising a magainin peptide as taught by Stevenson et al. and the antimicrobial and preservative properties of a peptide comprising SEQ ID NO: 4 as taught by

Maloy, it would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to use the peptide in Maloy in the emulsion for use as an antimicrobial preparation to treat disease or as an ophthalmic preservative. Thus, the claimed invention was prima facie obvious to make and use at the time the claimed invention was made.

Claims 81, 84-88, 91-105 and 110-112, 119 and 120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maloy in view of Stevenson as applied to claims 81, 84-88, 91-95, 98, 99, 101, 104-106 and 110-112 above, and further in view of Hunt. Hunt teaches an antimicrobial ophthalmic composition for contact lenses that is available for use in a multidose format (col. 8, lines 48-55) and has a liquid phase (col. 6, lines 13-15) and comprises one active agent only (col. 9, lines 10-11), for example, magainins, and a buffer to control the pH (col. 6, lines 25-26), wherein the active agent is present in an amount less than 10 milligrams per millimeter (col. 8, lines 32-35 and Example 1; for example, .1 mg of active agent in 5-10 ml of liquid) and comprises water from an added saline solution (col. 8, lines 37-40). The antimicrobial activity prevents the growth of microbes and serves to preserve the ophthalmic solution. Hunt does not teach an oil-in-water emulsion or a peptide of SEQ ID NO: 4.

Stevenson et al. teach an oil-in-water emulsion formulation to treat moderate-to-severe dry eye disease wherein the active agent cyclosporin in present in a therapeutically amount of a concentration of .05% (line 7), namely, liquid eye makeup remover (col. 24, lines 43-44) with a certain tonicity (present claim 98) wherein the composition comprises magainin (col. 22, lines 8-22) (present claim 99). Stevenson et al. do not teach a preparation containing a sole preservative or a peptide identical to SEQ ID NO: 4.

Maloy teaches an ophthalmic composition that is applied topically onto the eye (col. 29, lines 27-28 and col. 30, lines 53-55) (present claim 106) comprising a sole preservative (col. 28, lines 48-50 and Ex. 1), namely, therapeutically effective amount of magainin antimicrobial peptide identical to SEQ ID NO: 4 (see copy of attached sequence alignment; SEQ ID NO: 2 and col. 31, line 56) in a distilled water solution which also may serve as a tonicity component (col. 32 line 14) (present claims 81, 84-88, 91-95, 101, 104, 105, 110-112). Maloy does not teach an oil-in-water emulsion

Given the antimicrobial activity and preservative effects of magainin in an oil-in-water ophthalmic preparation comprising less than 10 mg per mm of magainin and a buffer to control the pH as taught by Stevenson et al. and the successful use of magainin peptide in SEQ ID NO: 4 as a preservative as taught by Maloy, it would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to use less than 10 mg per mm, a buffer, and an oil-in water emulsion with SEQ ID NO: 4 in ophthalmic preparation. Thus, the claimed invention was prima facie obvious to make and use at the time the claimed invention was made.

Claims 106-109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kross (US 5,993,864) in view of Malloy. Maloy teaches an ophthalmic composition that is applied topically onto the eye (col. 29, lines 27-28 and col. 30, lines 53-55) (present claim 106) comprising a sole preservative (col. 28, lines 48-50 and Ex. 1), namely, therapeutically effective amount of magainin antimicrobial peptide identical to SEQ ID NO: 4 (see copy of attached sequence alignment; SEQ ID NO: 2 and col. 31, line 56) in a distilled water solution. Maloy does not teach a composition that is a surgical irrigant.

Kross teaches an antibacterial composition (col. 1, lines 35-36) that may be applied to the eye (col. 3, lines 10-12) and that further may be used as a surgical irrigant (col. 3, lines 5-8). Kross does not teach a composition comprising magainin.

Given the success of using an antibacterial ophthalmic composition in the eye and as a surgical irrigant as taught by Kross, it would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to use the antimicrobial composition comprising magainin as taught by Maloy as a surgical irrigant. Thus, the claimed invention was prima facie obvious to make and use at the time the claimed invention was made.

Conclusion

Claims 81-120 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Mayes whose telephone number is (703) 605-1208. The examiner can normally be reached on Monday through Friday from 9 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

L. Mayes

Laurie Mayes
Patent Examiner
Art Unit 1653
July 16, 2003

Christopher S. F. Low

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